ONE-COMPONENT SELF-ETCHING ADHESIVE

RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 12/284,854 (now abandoned) filed Sep. 25, 2008 which is a continuation of U.S. application Ser. No. 11/545, 669 (now abandoned) filed Oct. 10, 2006 which is a continuation of U.S. application Ser. No. 11/432,928 (now abandoned) filed May 12, 2006, which is a continuation of U.S. application Ser. No. 11/402,127 (now abandoned) filed Apr. 10, 2006, which is a continuation of U.S. application Ser. No. 11/244,937 (now abandoned) filed Oct. 6, 2005 which claims benefit of U.S. Provisional Application Ser. No. 60/618,649 filed Oct. 14, 2004.

TECHNICAL FIELD

A one-part, self-etching dental adhesive having improved performance such as adhesion performance with a simple one-coat application, without the need of separate acid-etching, a priming pre-treatment, or bonding step. The invention provides such improvements due to a function of the pH balance of the system in combination with an acid stable photoinitiating system. More specifically, the performance and pH balance is achieved through the employment of a hydrolytically stable, acidic, high-strength adhesive monomer (such as PENTA), with a stable, bifunctional, hydrophilic monomer (such as AHPMA) that yields greater crosslinking.

BACKGROUND OF THE INVENTION

Typically, the procedure for dental composite restorations using a total etch adhesive involves acid etching the tooth using phosphoric acid followed by water rinsing and drying. Subsequently, a primer is applied and dried followed by the application of a bonding agent, which is light cured. Finally, the composite restoration is applied, cured and polished. Overall, there are many steps to complete a dental restoration. Unfortunately, with each additional step the process becomes more difficult increasing the risk for failure. In general, the primary goal of this project is to reduce the number of steps associated with the application of the dental adhesive.

In order to accomplish this objective, the number of components to be used for priming and bonding were combined into one-bottle as exemplified by the Prime & Bond® brand adhesive (Dentsply). However, etching must still be conducted prior to the application and curing of the single component priming. The process is further simplified by combining the priming and etching into a one-component self-etching system. For example, ClearFil SE Bond (Kuraray) is a 2-component system, which consists of a self-etching primer and bonding liquid. In this 2-step system the self-etching primer is applied followed by the application of the bonding agent.

ClearFil SE Bond is indicated for direct light cured composite restoration bonding only. For indirect restoration bonding, Kuraray recommends using ClearFil Liner Bond 2V that is a multi-component (Primers A and B, Bond Liquid A and B) which involves a multi-step application for self-etching adhesive system.

Similarly, Adper Prompt L-Pop (3M ESPE), a 2-component/one-pack/one-step self-etching priming adhesive, is supplied in a unit dose blister package that consists of two-predosed compartments, for the two liquids A and B. Prompt L-Pop is only indicated for bonding direct, light cured composite restorations.

The 1P-SEA product developed at L.D. Caulk further simplifies the technique for applying dental adhesives by incorporating the etching, priming and bonding components into a single component bottle or unit dose package. More specifically, the application technique is reduced from the complex series of events previously described to apply, dry and cure. The Caulk 1P-SEA is differentiated from the only currently marketed single component self-etching adhesive (i-Bond Heraeus Kulzer), through chemistry (see Table 1 for preferred formulation and raw material ranges) and performance (see Tables 2-7). It exhibits performance (microleakage and shear bond strength) which is superior to i-Bond and comparable to the leading 2-component systems available in the dental market.

Ref. U.S. Pat. No. 6,387,979 by K. Hino (Kuraray Co. Ltd., Japan), issued May 14, 2002.

Abstract: A tooth treated with a bonding composition with high initial bonding strength and good bonding durability comprising a mixture of polymerizable compound having an acid group, a water-soluble film-forming agent, water, and a curing agent, in which the calcium salt of the acid is insoluble in water, and the film-forming agent is a polymerizable compound miscible with a physiological saline solution, does not require any pre-treatment such as acid-etching or priming treatment.

This patent states that the active ingredients of the composition in a single package may degrade or polymerize while stored. To prevent this, the constituent ingredients of the composition may be divided into two or more parts. The plural parts are separately packaged and stored in different packages. For their use, the plural parts taken out of the individual packages may be applied to one and the same object in sequence; or they may be blended into one mixture just before use.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** compares that 24 hour bond strength of the composite disclosed herein to human enamel and dentin with various self-etching adhesive.

FIG. **2** compares thermal cycled bond strength of the composite disclosed herein to human enamel and dentin with various self-etching adhesives.

FIG. **3** compares thermal cycled enamel and dentin to composite use the self-etching adhesive disclosed herein.

FIG. **4** compares the 24 hour indirect bond strength of a self-cure adhesive and a resin cement to human teeth.

SUMMARY OF THE INVENTION

1P-SEA materials according to the invention can achieve good adhesion performance with a simple one-coat application, without the need of using phosphoric acid tooth gel.

PREFERRED EMBODIMENTS FOR CARRYING OUT THE INVENTION

For One-component Visible Light Cure Self-Etching Adhesive (1P-SEA) according to the invention, it is indicated to bond VLC composite/compomer direct restorations to human teeth substrate (enamel and dentine) without the need of separate acid-etching or priming pre-treatment teeth bonding step. When used with a separate Self-Cure Activator component, the 1P-SEA can also bond for cemented indirect